

CLAIMS:

1. A composition comprising:

a substance that modulates the status of 108P5H8, or a molecule that is modulated by

5 108P5H8 whereby the status of a cell that expresses 108P5H8 is modulated.

2. The composition of claim 1, further comprising a pharmaceutically acceptable carrier.

10 3. A pharmaceutical composition that comprises the composition of claim 1 in a human unit dose form.

4. A composition of claim 1 wherein the substance comprises an antibody or fragment thereof that specifically binds to a 108P5H8-related protein.

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5. The antibody or fragment thereof of claim 4, which is monoclonal.

6. A recombinant protein comprising an antigen-binding region of a monoclonal antibody of claim 5.

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7. The antibody or fragment thereof of claim 4, which is labeled with a detectable marker.

8. The recombinant protein of claim 6, which is labeled with a detectable  
25 marker.

9. The antibody fragment of an antibody of claim 4, which is an Fab, F(ab')<sub>2</sub>, Fv or sFv fragment.

30 10. The antibody of claim 4, which is a human antibody, a humanized antibody or a chimeric antibody.

11. A non-human transgenic animal that produces an antibody of claim 4.

12. A hybridoma that produces an antibody of claim 5.

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13. A single chain monoclonal antibody that immunospecifically binds to a 108P5H8-related protein, and that comprises the variable domains of the heavy and light chains of a monoclonal antibody of claim 5.

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14. A vector comprising a polynucleotide that encodes a single chain monoclonal antibody of claim 13.

15. A method of delivering a cytotoxic agent or a diagnostic agent to a cell that expresses 108P5H8, said method comprising:

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providing the cytotoxic agent or the diagnostic agent conjugated to an antibody or fragment thereof of claim 4; and,

exposing the cell to the antibody-agent or fragment-agent conjugate.

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16. A composition of claim 1 wherein the substance comprises a polynucleotide that encodes an antibody or fragment thereof either of which immunospecifically binds to an 108P5H8-related protein.

17. A composition of claim 3 wherein the substance comprises a 108P5H8-related protein.

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18. The composition of claim 17, further comprising antigen presenting cells.

19. The composition of claim 1 wherein the substance comprises an analog of a peptide of eight, nine, ten, or eleven contiguous amino acids of Figure 2 (SEQ ID NO.:

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\_\_\_\_\_).

20. A composition of claim 1 wherein the substance comprises a CTL polypeptide epitope of the amino acid sequence of Figure 2 (SEQ ID NO.: \_\_\_\_), with a *proviso* that the epitope is not the entire amino acid sequence of Figure 2 (SEQ ID NO.: \_\_\_\_).

21. The composition of claim 20 wherein the CTL epitope comprises a polypeptide selected from Tables V-XVIII, XXII, and XXIII, with a *proviso* that the epitope is not the entire amino acid sequence of Figure 2 (SEQ ID NO.: \_\_\_\_).

22. A composition of claim 1 wherein the substance comprises an antibody polypeptide epitope of the amino acid sequence of Figure 2 (SEQ ID NO.: \_\_\_\_), with a *proviso* that the epitope is not the entire amino acid sequence of Figure 2 (SEQ ID NO.: \_\_\_\_).

23. A composition of claim 22 wherein the antibody epitope comprises a peptide region of at least 5 amino acids of Figure 2 (SEQ ID NO.: \_\_\_\_) in any whole number increment up to 875 that includes an amino acid position selected from: an amino acid position having a value greater than 0.5 in the Hydrophilicity profile of Figure 5, an amino acid position having a value less than 0.5 in the Hydropathicity profile of Figure 6; an amino acid position having a value greater than 0.5 in the Percent Accessible Residues profile of Figure 7; an amino acid position having a value greater than 0.5 in the Average Flexibility profile on Figure 8; or an amino acid position having a value greater than 0.5 in the Beta-turn profile of Figure 9, with a *proviso* that the epitope is not the entire amino acid sequence of Figure 2 (SEQ ID NO.: \_\_\_\_).

24. The recombinant protein of claim 23, which comprises murine antigen binding region residues and human constant region residues.

25. A polynucleotide that encodes an analog peptide of claim 19.

26. A composition of claim 1 wherein the substance comprises a polynucleotide that comprises an 108P5H8-related protein coding sequence, with a *proviso* that the coding sequence does not encode the entire amino acid sequence of Figure 2 (SEQ ID NO.: \_\_\_\_).

5 27. The composition of claim 26 in human unit dose form.

28. A composition of claim 26 comprising a polynucleotide from position number 44 through number 2671 of Figure 2 (SEQ ID NO.: \_\_\_\_).

10 29. The composition of claim 28 wherein T is substituted with U.

30. A composition of claim 32 that comprises the coding sequence for the polynucleotide of Figure 2 (SEQ ID NO.: \_\_\_\_).

15 31. The composition of claim 30 wherein T is substituted with U.

32. A composition of claim 26 comprising a polynucleotide that encodes an 108P5H8-related protein that is at least 90% homologous to the entire amino acid sequence shown in Figure 2 (SEQ ID NO.: \_\_\_\_).

20 33. The composition of claim 32 wherein the polynucleotide encodes an 108P5H8-related protein that is at least 90% identical to the entire amino acid sequence shown in Figure 2 (SEQ ID NO.: \_\_\_\_).

25 34. A composition of claim 26 wherein the substance comprises a polynucleotide that encodes at least one peptide set forth in Tables V-XVIII, XXII, and XXIII, with a *proviso* that the amino acid sequence of Figure 2 is not encoded.

30 35. A composition of claim 26 comprising a polynucleotide that encodes a peptide region of at least 5 amino acids of Figure 2 (SEQ ID NO.: \_\_\_\_) that includes an amino acid position selected from: an amino acid position having a value greater than 0.5 in the

Hydrophilicity profile of Figure 5, an amino acid position having a value less than 0.5 in the Hydropathicity profile of Figure 6; an amino acid position having a value greater than 0.5 in the Percent Accessible Residues profile of Figure 7; an amino acid position having a value greater than 0.5 in the Average Flexibility profile on Figure 8; or an amino acid position having a value greater than 0.5 in the Beta-turn profile of Figure 9, with a *proviso* that the entire amino acid sequence of Figure 2 (SEQ ID NO.: \_\_\_\_ ) is not encoded.

36. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 26.

37. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 28.

38. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 29.

39. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 30, in human unit dose form.

40. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 31.

41. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 32.

42. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 33.

43. A composition comprising a polynucleotide that is fully complementary to a polynucleotide of claim 34.

44. A pharmaceutical composition of claim 1 wherein the substance comprises a ribozyme that cleaves a polynucleotide having 108P5H8 coding sequence and a physiologically acceptable carrier.

5 45. A pharmaceutical composition of claim 1 wherein the substance comprises a nucleic acid molecule that encodes a ribozyme that cleaves a polynucleotide having 108P5H8 coding sequence and a physiologically acceptable carrier.

10 46. A pharmaceutical composition of claim 1 wherein the substance comprises human T cells, wherein said T cells specifically recognize a 108P5H8 peptide sequence in the context of a particular HLA molecule.

47. A method of inhibiting growth of cancer cells that expresses 108P5H8, the method comprising:

15 administering to the cells the composition of claim 1.

48. A method of claim 47 of inhibiting growth of cancer cells that express 108P5H8, the method comprising steps of:

20 administering to said cells an antibody or fragment thereof either of which specifically bind to a 108P5H8-related protein.

49. A method of claim 47 of inhibiting growth of cancer cells that express 108P5H8, the method comprising steps of:

25 administering to said cells a vector that encodes a single chain monoclonal antibody that immunospecifically binds to an 108P5H8-related protein.

50. A method of claim 47 of inhibiting growth of cancer cells that express 108P5H8, the method comprising steps of:

administering to said cells an 108P5H8-related protein.

51. A method of claim 47 of inhibiting growth of cancer cells that express 108P5H8, the method comprising steps of:

administering to said cells a vector that comprises a polynucleotide comprising a 108P5H8-related protein coding sequence.

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52. A method of claim 47 of inhibiting growth of cancer cells that express 108P5H8, the method comprising steps of:

administering to said cells an antisense polynucleotide complementary to a polynucleotide having a 108P5H8 coding sequence.

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53. A method of claim 47 of inhibiting growth of cancer cells that express 108P5H8, the method comprising steps of:

administering to said cells a ribozyme that cleaves a polynucleotide having 108P5H8 coding sequence.

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54. A method of claim 47 of inhibiting growth of cancer cells that express 108P5H8 and a particular HLA molecule, the method comprising steps of:

administering to said cells human T cells, wherein said T cells specifically recognize an 108P5H8 peptide sequence in the context of the particular HLA molecule.

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55. A method of treating a patient who bears cancer cells that express 108P5H8, the method comprising:

administering to the patient the composition of claim 1.

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56. A method of claim 55 for treating a patient who bears cancer cells that expresses 108P5H8, the method comprising steps of:

administering to said patient an antibody or fragment thereof either of which specifically binds to a 108P5H8-related protein.

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57. A method of claim 55 for treating a patient who bears cancer cells that expresses 108P5H8, the method comprising steps of:

administering to said patient a vector that encodes an antibody or fragment thereof either of which immunospecifically bind to an 108P5H8-related protein.

58. A method of claim 57 for treating a patient with a cancer that expresses  
5 108P5H8, the method comprising steps of:

administering to said patient a vector that delivers a single chain monoclonal antibody coding sequence, whereby the encoded single chain antibody is expressed intracellularly within cancer cells that express 108P5H8.

10 59. A method of claim 55 for treating a patient who bears cancer cells that express 108P5H8, the method comprising steps of:

administering to said patient an 108P5H8-related protein.

15 60. A method of claim 55 for treating a patient who bears cancer cells that express 108P5H8, the method comprising steps of:

administering to said patient a vector that comprises a polynucleotide comprising a 108P5H8-related protein coding sequence.

20 61. A method of claim 55 for treating a patient who bears cancer cells that express 108P5H8, the method comprising steps of:

administering to said patient an antisense polynucleotide complementary to a polynucleotide having a 108P5H8 coding sequence.

25 62. A method of claim 55 for treating a patient who bears cancer cells that express 108P5H8, the method comprising steps of:

administering to said patient a ribozyme that cleaves a polynucleotide having an 108P5H8 coding sequence.

30 63. A method of claim 55 for treating a patient who bears cancer cells that express 108P5H8, the method comprising steps of:



administering to said patient a nucleic acid molecule that encodes a ribozyme that cleaves a polynucleotide having an 108P5H8 coding sequence.

64. A method of claim 55 for treating a patient who bears cancer cells that express 108P5H8 and a particular HLA molecule, the method comprising steps of:  
administering to said patient human T cells, wherein said T cells specifically recognize an 108P5H8 peptide sequence in the context of the particular HLA molecule.

65. A method of generating a mammalian immune response directed to 108P5H8, the method comprising:  
exposing cells of the mammal's immune system to an immunogenic portion of  
a) an 108P5H8-related protein and/or  
b) a nucleotide sequence that encodes said protein,  
whereby an immune response is generated to 108P5H8.

66. A method of inducing an immune response of claim 65, said method comprising:  
providing a 108P5H8-related protein that comprises at least one T cell or at least one B cell epitope;  
contacting the epitope with a mammalian immune system T cell or B cell respectively, whereby the T cell or B cell is induced.

67. The method of claim 66 wherein the immune system cell is a B cell, whereby the induced B cell generates antibodies that specifically bind to the 108P5H8-related protein.

68. The method of claim 66 wherein the immune system cell is a T cell that is a cytotoxic T cell (CTL), whereby the activated CTL kills an autologous cell that expresses the 108P5H8-related protein.

69. The method of claim 66 wherein the immune system cell is a T cell that is a helper T cell (HTL), whereby the activated HTL secretes cytokines that facilitate the cytotoxic activity of a cytotoxic T cell (CTL) or the antibody producing activity of a B cell.

5 70. An assay for detecting the presence of a 108P5H8-related protein or polynucleotide in a biological sample from a patient who has or who is suspected of having cancer, comprising steps of:

contacting the sample with a substance of claim 1 that specifically binds to the 108P5H8-related protein or polynucleotide, respectively; and,

10 determining that there is a complex of the substance and 108P5H8-related protein or the substance and 108P5H8-related polynucleotide, respectively.

71. An assay of claim 70 for detecting the presence of a 108P5H8-related protein in a biological sample from a patient who has or who is suspected of having cancer,  
15 comprising steps of:

contacting the sample with an antibody or fragment thereof either of which specifically bind to the 108P5H8-related protein; and,

determining that there is a complex of the antibody or fragment thereof and 108P5H8-related protein.

20 72. The assay in accordance with claim 70 further comprising a step of: taking a sample from a patient who has or who is suspected of having cancer.

73. The assay of claim 70 for detecting the presence of an 108P5H8  
25 polynucleotide in a biological sample, comprising:

contacting the sample with a polynucleotide probe that specifically hybridizes to the polynucleotide of Figure 2 (SEQ ID NO.: \_\_\_\_); and,

30 detecting the presence of a hybridization complex formed by the hybridization of the probe with 108P5H8 polynucleotide in the sample, wherein the presence of the hybridization complex indicates the presence of 108P5H8 polynucleotide within the sample.

74. An assay in accordance with claim 70 for detecting the presence of 108P5H8 mRNA in a biological sample from a patient who has or who is suspected of having cancer, said method comprising:

producing cDNA from the sample by reverse transcription using at least one primer;

5 amplifying the cDNA so produced using 108P5H8 polynucleotides as sense and antisense primers, wherein the 108P5H8 polynucleotides used as the sense and antisense primers are capable of amplifying 108P5H8 cDNA; and

detecting the presence of the amplified 108P5H8 cDNA.

10 75. A method for monitoring 108P5H8 gene products in a biological sample from a patient who has or who is suspected of having cancer, the method comprising:

determining the status of 108P5H8 gene products expressed by cells in a tissue sample from an individual;

15 comparing the status so determined to the status of 108P5H8 gene products in a corresponding normal sample; and,

identifying the presence of aberrant 108P5H8 gene products in the sample relative to the normal sample.

20 76. A method of monitoring the presence of cancer in an individual comprising: performing the method of claim 75 whereby the presence of elevated gene products 108P5H8 mRNA or 108P5H8 protein in the test sample relative to the normal tissue sample indicates the presence or status of a cancer.

25 77. The method of claim 76 wherein the cancer occurs in a tissue set forth in Table I.